DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2014

Covidien
Ms. Laura Moen-Ftacek
Regulatory Affairs Product Manager
3033 Campus Drive
Plymouth, Minnesota 55441

Re: K141858
Trade/Device Name: ClosureRFG Radiofrequency Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 9, 2014
Received: July 10, 2014

Dear Ms. Ftacek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

ClosureRFG Radiofrequency Generator

Indications for Use *(Describe)*

The ClosureRFG generator is used with radiofrequency catheters intended for vessel and tissue coagulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

ClosureRFG™ Radiofrequency Generator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1 Submitter Information

Applicant	Covidien 3033 Campus Drive Plymouth, MN 55441 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Laura Moen-Ftacek Regulatory Affairs Product Manager
Date Prepared	July 9, 2014

2 Subject Device

Device Trade Name	ClosureRFG™ Radiofrequency Generator
Classification Name	Electrosurgical cutting and coagulation device and accessories
Classification Regulation	21 CFR 878.4400
Product Code	GEI
Classification Panel	General and Plastic Surgery

3 Predicate Devices

Device Trade Name	VNUS™ Radio Frequency Generator – RFGPlus Model RFG2
510(k) Number	K040638
510(k) Clearance Date	June 7, 2004

4 Device Description

The ClosureRFG Radiofrequency Generator (RFG3) is designed to provide controlled delivery of radiofrequency (RF) energy to RF catheters marketed by Covidien. The RFG3 is for use with the ClosureFast™ endovenous radiofrequency catheters and ClosureRFS™ endovenous radiofrequency stylet, intended for vessel and tissue coagulation.

The RFG3 supplies, measures, and displays RF output power, load impedance (displayed for ClosureRFS only), and elapsed time of RF delivery. The RFG3 also interfaces with a sensor in the catheter to provide a continuous display of measured temperature during RF delivery.

5 Indications for Use

The ClosureRFG generator is used with radiofrequency catheters intended for vessel and tissue coagulation.

6 Comparison of Technological Characteristics

The proposed RFG3 is substantially equivalent to the currently marketed VNUS Radio Frequency Generator – RFGPlus Model RFG2 (K040638). The proposed and predicate devices share the following technological characteristics:

- Indications for Use/Intended Use
- Fundamental Scientific Technology
- Principles of Operation
- Compatibility with commercially available RF Catheters

Modifications have been made the generator enclosure and to the overall user interface to increase the ease of use of the device and provide a state of the art user experience. They do not impact the safety and effectiveness of the device.

7 Performance Testing Summary

To demonstrate substantial equivalence of the proposed RFG3 to the predicate device, the following design verification and validation testing was performed:

- Mechanical
- Mechanical Strength
- Electrical
- Thermal
- Environmental
- Electromagnetic Compatibility and Electrical Safety
- Thermal
- Environmental
- Packaging Integrity
- Software Verification and Validation
- Simulated Use
- Tissue Model

The results of the testing demonstrate that the RFG3 meets all requirements and has comparable performance to the predicate device.

8 Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, Covidien considers the proposed RFG3 to be substantially equivalent to the currently marketed VNUS Radio Frequency Generator – RFGPlus Model RFG2 (K040638).